

National Institute for Health and Clinical Excellence

Clinical guideline: Lower Urinary Tract Symptoms in men

PRE-PUBLICATION CHECK ERROR TABLE

Organisation	Order number	Section number in FULL guideline	Page number	ERROR REPORT	RESPONSE
Welsh Assembly Government	1	General		We have no comments to submit at this stage.	Thank you for your comment.
Medtronic Limited	1	General		<p>Medtronic would wish to renew their concerns about the comments made in the draft stage of the process being dismissed on the basis of being out with the scope.</p> <p>The technology that Medtronic fed back on was Sacral Nerve Stimulation (in scope, well established, well evidenced) and the dismissals of comments were made on the basis of Tibial Nerve Stimulation (completely different technology, unproven, different site of action, differing anatomical pathways).</p> <p>The detail of our objections which we would ask to be considered as factual errors relate to the feedback on our comments made at the draft stage are below:</p> <p>Comment 2,3,5,6 were dismissed on the basis that Percutaneous tibial nerve stimulation was not in the scope of the guideline. Medtronic's comments are all related to our technology for sacral nerve stimulation which is in the scope. We would request these comments are reviewed.</p> <p>Any confusion that may have arisen around the "TNE" mentioned in our submission related to the <i>test of the sacral nerve pathway</i> via a percutaneous needle insertion of an electrode which is then connected to a</p>	<p>Thank you for your comments. We apologise for any misunderstanding regarding these comments. We have reconsidered comments 2, 3, 5 and 6 and updated the responses in the stakeholder consultation table. Comments 4, 7, 8 and 18 relate to issues other than factual error and we cannot respond to them.</p>

			<p>generator that the patient wears for a period of time - if the response to the test stimulation is successful then a permanent implant procedure is undertaken.</p> <p>Comment 4 was dismissed incorrectly. Sacral nerve stimulation is indicated for urge incontinence and urge frequency due to detrusor over activity, it is not indicated nor promoted for the stress urinary incontinence nor bladder outlet obstruction which was the basis the comment was dismissed. The nerve pathways for sacral nerve stimulation of the detrusor muscle are the same in men and women and so we feel this comment was ruled out without full understanding of the technology and would request it is reconsidered.</p> <p>Comment 7 was dismissed based on the inclusion criteria which was incorrectly assessed in point 4 and mentioned again in point 8. There are long term studies as mentioned that we would wish to be considered on the basis of the sacral nerve pathway. We invite you to re-examine your comment</p> <p>Comment 8 again revolves around the inclusion criteria for studies, in the light of sacral nerve pathways being functionally identical in men and women stimulation we would invite you to reconsider.</p> <p>Comment 18 The key question of battery life remains critical to the value of the technology and the cost. The Medtronic implant is the only sacral nerve stimulator on the market and we feel reference to the 7 year battery life would help to inform the decision of commissioners, we would invite you to reconsider this comment.</p> <p>The original comments on the draft and the GDG replies are below for reference</p>	
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Royal College of Nursing	1	General		There are no further comments to make on this document	Thank you for your comment.
NICE Technical Adviser	1	2.6.2	48	Para 1. NICE guidelines can now state that they are using GRADE and do not need to qualify it by saying GRADE has been adapted or modified. This is because the criteria for stating that an organisation uses GRADE were discussed at a recent GRADE meeting and NICE fulfils them.	Thank you for your comment. We have amended the text accordingly.
Royal College of Physicians	1	4.8	87	We are surprised that the measures for assessment of renal function recommended in this guideline are only two: serum creatinine, and estimation of glomerular filtration rate by creatinine clearance [which involves a 24 hour urine collection]. Automatic estimation of GFR [eGFR] using serum creatinine and the MDRD formula entered clinical practice in the UK five years ago, and is now routinely reported in all clinical laboratories. The recommendations of the NICE Guideline on Chronic Kidney Disease are based on the correct use and interpretation of eGFR using this method. It is therefore surprising that this guideline makes no mention of eGFR, and recommends a method for estimating GFR, creatinine clearance, which is outdated and inconsistent with other NICE guidance.	Thank you for pointing this out. We have corrected this by removing reference to 'creatinine clearance' in the text. We have referred to serum creatinine and estimation of GFR in the paragraph 4.8 on renal function. We have amended the recommendation to include eGFR.
Royal College of Physicians	2	4.8	General	The section implies that a creatinine clearance is a more accurate measure of renal function than an estimated GFR from a serum creatinine. This is not the case and the literature is quite clear that using calibrated serum creatinine eGFR has greater diagnostic accuracy than creatinine clearance (and all our labs use creatinine calibrated to the IDMS methodology through participation in UKNEQAS). The guideline frequently refers to 'renal impairment' but nowhere in the guideline is this defined in terms of renal function, this is also apparent in the algorithms where 'abnormal' is a decision box but abnormal is not	Thank you for pointing this out. We have removed reference to creatinine clearance from the text. Defining 'abnormal' renal function relates to an issue other than a factual error. Therefore, we cannot respond to it.

				defined.	
Uromedica Inc.	1	9.1	283	<p>In line 13, it is stated that <i>in theory</i> the amount of fluid can be either increased or decreased to achieve continence without voiding difficulty.</p> <p>This is not just in theory, but also in practice. More than 7,000 patients have been treated to date (mostly in continental Europe) and balloon volume has been adjusted to improve continence without causing voiding difficulty. More than 10 articles published in peer reviewed journals support this statement. No articles (or presentations at scientific meetings) suggest that this is not the case.</p>	Thank you for your comment. We agree and have amended the text accordingly.